

Notice of Allowability

Application No.

10/692,855

Applicant(s)

RYDE ET AL.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to october 10, 2007.
2. ☒ The allowed claim(s) is/are 136,140-184,186-239,241-294 and 296-537.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

SHELLEY A. DODSON
PRIMARY EXAMINER

DETAILED ACTION

Claims 136, 140-184, 186-239, 241-294 and 296-537 are pending in this application.

Action Summary

1. The examiner acknowledges the cancellation of claims 185, 240 and 295. Therefore, any and all objections and/or rejections directed to them are hereby withdrawn.
2. The provisional rejection of claims 136, 140-184, 186-239, 241-294 and 296-303 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 136, 140-178 and 183-331 of copending application 10/444,066 is hereby withdrawn as applicant has filed a terminal disclaimer.
3. The rejection of claims 136, 140-184, 186-239, 241-294 and 296-303 under 35 U.S.C. 112, second paragraph as being indefinite is hereby withdrawn in view of amendment to the claims:

Statement of Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance:

The claims are allowable over the cited prior art because the prior art does not teach, disclose nor make obvious a method of treating a condition selected from the group listed in claim 136 comprising a stable fenofibrate composition comprising particles of fenofibrate having a D50 particle size of less than 500 nm, a D90 particle size less than 700 nm or the claimed dosage amount and at least one surface stabilizer. The closest

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prior art references of Pace et al. (US 6,696,084), Liu et al. (U.S. 6,368,620) and Mishra et al. (WO 99/29300) do not teach the claimed invention. The claims are directed to particles of fenofibrate having a D50 particle size of less than 500 nm and at least one surface stabilizer. Neither, Liu et al. or Mishra et al. teach that 50% of the particles have a particle size of less than 500 nm. Liu et al. teach the particles and a stabilizer, however, the stabilizers that are taught in the composition of Liu et al. are not the same stabilizers, which are being claimed by applicant. The claims are also directed to particles of fenofibrate having a D90 particle size of less than 700 nm and at least one surface stabilizer. Neither, Liu et al. or Mishra et al. teach that 90% of the particles have a particle size of less than 700 nm. The claims disclose a composition comprising particles of fenofibrate having a particle size of about 500nm, contained in a capsule containing 145mg of fenofibrate. The closest prior art reference of Liu et al. teach a maximum dosage amount of 100mg. It is not taught or suggested to increase the dosage amount to 145mg. Pace et al. contains a phospholipid compound and therefore it teaches away from the claimed invention. Furthermore, none of the cited prior art references teach an increased bioavailability and a decreased fed-fast variable as taught in applicants' specification.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

5. Claims 136, 140-184, 186-239, 241-294 and 296-537 are allowed.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George
Art Unit 1616


SHELLEY A. DODSON
PRIMARY EXAMINER

Johann R. Richter
Supervisory Patent Examiner
Art Unit 1616


Johann R. Richter